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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,293	12/31/2003	Sangeeta N. Bhatia	36796-502C01US	9194
35437 7590 09/17/2010 MINTZ LEVIN COHN FERRIS GLOVSKY & POPEO ONE FINANCIAL CENTER BOSTON, MA 02111				
EXAMINER TENTON, LEO B				
ART UNIT		PAPER NUMBER		
1791				
MAIL DATE		DELIVERY MODE		
09/17/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/750,293

**Applicant(s)**

BHATIA ET AL.

**Examiner**

Leo B. Tentoni

**Art Unit**

1791

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 30, 31, 34, 38-46, 48, 49, 53-61 and 63-66 is/are pending in the application.
- 4a) Of the above claim(s) 39-44 and 54-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30, 31, 34, 38, 45, 46, 48, 49, 53, 60, 61 and 63-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. Claims 39-44 and 54-59 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 20 April 2007.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 64 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 64 has been amended to depend from claim 40, which has been withdrawn from further consideration due to a requirement for restriction. Therefore, claim 64 does not further limit the subject matter of any preceding claim currently under consideration.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the

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differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 30, 34, 38, 45, 46, 48, 49, 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al (U.S. Patent 6,143,293 A) in combination with Kale et al (U.S. Patent Application Publication 2002/0127711 A1).

Weiss et al (see the entire document, in particular, col. 1, line 15 to col. 2, line 18; col. 4, line 39 to col. 5, line 8; col. 6, lines 1-51; Examples) teaches a layered polymer scaffold including two or more assembled polymer membranes, wherein the scaffold has a thickness of about one (1) millimeter and each membrane has a surface with varying topology including at least one organized feature with at least one dimension of about 25 to 250 microns. Weiss et al teaches that the scaffold is made of a

polymer material, but does not explicitly teach a synthetic polymer (or biopolymer) of a hydrogel. Kale et al (see the entire document, in particular, paragraphs [0112] - [0116], [0118] and [0125] - [0132]) teaches a scaffold made of a synthetic polymer (or biopolymer) of a hydrogel, and it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a synthetic polymer (or biopolymer) of a hydrogel as a scaffold material in the scaffold of Weiss et al in view of Kale et al in order to provide a scaffold for use in the repair or replacement of tissue.

7. Claims 31, 53, 60, 63 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al (U.S. Patent 6,143,293 A) in combination with Kale et al (U.S. Patent Application Publication 2002/0127711 A1).

Weiss et al (see the entire document, in particular, col. 1, line 15 to col. 2, line 18; col. 4, line 39 to col. 5, line 8; col. 6, lines 1-51; Examples) teaches a polymer scaffold including at least one membrane, wherein the scaffold has a thickness of about one (1) millimeter and each membrane has a surface with varying topology including at least one organized feature with at least one dimension of about 25 to 250 microns. Weiss et al teaches that the scaffold is made of a polymer material, but does not explicitly teach a synthetic polymer (or biopolymer). Kale et al (see the entire document, in particular, paragraphs [0112] - [0116], [0118] and [0125] - [0132]) teaches a scaffold made of a synthetic polymer (or biopolymer), and it

would have been obvious to one of ordinary skill in the art at the time the invention was made to use a synthetic polymer (or biopolymer) as a scaffold material in the scaffold of Weiss et al in view of Kale et al in order to provide a scaffold for use in the repair or replacement of tissue.

8. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al (U.S. Patent 6,143,293 A) in combination with Kale et al (U.S. Patent Application Publication 2002/0127711 A1) as applied to claims 31, 53, 60, 63 and 66 above, and further in view of Masini et al (U.S. Patent Application Publication 2001/0043918 A1).

Weiss et al teaches a polymer scaffold including two or more assembled polymer membranes, but does not explicitly teach that the polymer membrane is a mesh. Masini et al (see the entire document, in particular, paragraphs [0027] - [0029] and [0086]) teaches a polymer scaffold including a membrane which may be a mesh, and such would have been obvious to one of ordinary skill in the art at the time the invention was made in Weiss et al in view of Masini et al in order to provide a scaffold for use in the repair or replacement of tissue.

#### ***Response to Arguments***

9. Applicant's arguments with respect to claims 30, 31, 34, 38, 45, 46, 48, 49, 53, 60, 61 and 63-66 have been considered but are moot in view of the new ground(s) of rejection.

10. Weiss et al teaches a scaffold including a membrane having a surface with varying topology including at least one feature

having a dimension of about 10 to 100 microns (see col. 8, line 39 to col. 9, line 46 of Weiss et al).

**Conclusion**

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leo B. Tentoni whose telephone number is (571) 272-1209. The examiner can normally be reached on Monday - Friday (6:30 A.M. - 3:00 P.M.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina A. Johnson can

be reached on (571) 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leo B. Tentoni/  
Primary Examiner, Art Unit 1791